REMARKS

Claims 1-19 are pending in the subject application. The Examiner stated that claims 2-9, 11 and 12 are withdrawn from consideration and claim 16 is drawn to a non-elected species. Applicants have hereinabove amended claim 1. Support for this amendment may be found inter alia in the specification on page 2, lines 7-19. The remaining changes to claim 1 merely introduce minor grammatical and format changes. This amendment does not involve any issue of new matter. Therefore, entry of this amendment is respectfully requested such that claims 1, 10 and 13-19 will be pending.

Rejections Under 35 U.S.C. §102

The Examiner rejected claims 1, 10, 17-19 under 35 U.S.C. §102 as being clearly anticipated by Rodgers et al., or Ballas et al. in light of Lori et al.

The Examiner stated that the claims are allegedly directed to a one step method of treatment of a subject with sickle cell disease comprising administering an amount of an antiviral agent effective to prevent sickling.

The Examiner stated that Rodgers et al. disclose administration of the antiviral compound, hydroxyurea, to patients with sickle cell disease.

The Examiner stated that Ballas et al. disclose administration of hydroxyurea improves rheological properties of red cells of

patients with sickle cell disease.

The Examiner stated that Lori et al. disclose that hydroxyurea has antiviral effects, therefore, it can be termed to be an antiviral agent.

In response, applicants respectfully traverse. Nevertheless, without conceding the correctness of the Examiner's rejection but to expedite prosecution of the subject application, applicants have hereinabove amended claim 1. Applicants point out that newly amended claim 1 excludes hydroxyurea as a claimed antiviral agent. In view of the above remarks, applicants maintain that claims 1, 10 and 17-19 satisfy the requirements of 35 U.S.C. §102(a) and respectfully request that the Examiner reconsider and withdrawn this ground of rejection.

The Examiner rejected claims 1, 10, 13-15 and 17-19 under 35 U.S.C. §102(b) as allegedly being anticipated by Lawson et al. The Examiner stated that Lawson et al. disclose administering acyclovir to a man with sickle cell trait. The Examiner stated that the oral dosage is 800 mg x 5. The Examiner stated that if the person weighed about 100 kg, this would be a dosage of about 400 mg/kg/day. The Examiner stated that because the patient is the same, namely a person afflicted with sickle cell disease, the compound administered is the same, acyclovir, and the amount administered falls within the ranges given in the specification on page 7 for an oral dosage as being an effective dose, the result of the treatment must necessarily, inherently be the same.

In response, applicants respectfully traverse the Examiner's rejection. Briefly, newly amended claim 1 provides a method of treating sickle cell disease in a subject comprising administering to the subject an amount of an antiviral agent effective to inhibit sickling of an erythrocyte in the subject.

Lawson et al. describe the administration of acyclovir to a patient in order to treat his infection with herpes simplex 1 and 2 and/or varicella zoster. The fact that the patient was afflicted with sickle cell disease did not prompt the doctors to administer the acyclovir. Therefore, the acyclovir was not administered to treat sickle cell disease. Furthermore, nowhere in Lawson et al. is it mentioned that acyclovir is administered to prevent sickling of an erythrocyte cell in the patient. Lawson et al. therefore do not teach the administration of acyclovir to treat sickle cell disease by inhibiting sickling of a cell, and thus fail to teach each and every element of the rejected claims. In view of the above remarks, applicants maintain that claims 1, 10, 13-15 and 17-19 satisfy the requirements of 35 U.S.C. §102(b) and respectfully request that the Examiner reconsider and withdraw this ground of rejection.

Rejections Under 35 U.S.C. §103(a)

The Examiner rejected claims 1, 10, 13-15 and 17-19 under 35 U.S.C. §103(a) as allegedly being unpatentable over U.S. 5,939,456. The Examiner stated that U.S. 5,939,456 discloses

administering acyclovir (col. 24, I. 31) to patients with blood disorders such as sickle cell disease (col. 1, I. 3) in combination with compositions that stimulate fetal hemoglobin expression. The Examiner stated that although the disclosure makes no mention of acyclovir's activity in the inhibition of the aggregation of hemoglobin S as is instantly disclosed, and is not administered for the same reason as the instant administration, the fact remains that the administration of acyclovir to the patients suffering from sickle cell disease in hemoglobin expression would inherently have the same effect as the instantly claimed effect in the absence of evidence to the contrary.

In response to the Examiner's rejection, applicants respectfully traverse, and maintain that the Examiner has failed to establish a prima facie case of obviousness against the rejected claims.

Briefly, claims 1, 10, 13-15, 17-19 provide a method for treating sickle cell disease in a subject comprising administering to the subject an amount of an antiviral agent effective to inhibit sickling of a cell in the subject.

To establish a prima facie case of obviousness, the Examiner must demonstrate three things with respect to each claim. First, the cited references, when combined, teach or suggest each element of the claim. Second, one of ordinary skill would have been motivated to combine the teachings of the cited references at the time of the invention. And third, there would have been a reasonable expectation that the claimed

invention would succeed.

Applicants note that the Examiner has cited only one reference in support of this rejection, i.e. U.S. Patent No. 5,939,456 ('456 patent).

The reference cited against the rejected claims fails to support a prima facie case of obviousness.

The '456 patent teaches pulse administration of compositions for the treatment of blood disorders (i.e. sickle cell disease) and cell proliferative disorders (i.e. neoplasia) (see abstract). The only description of antiviral agents (col. 24, line 31) is found in connection with the discussion of cancer treatment (see col. 22, line 42 - col. 25, line 9), not treatment of sickle cell anemia. Contrary to the Examiner's assertions therefore it would not be obvious from the '456 patent to administer antiviral agents to treat sickle cell disease.

To support a case of prima facie obviousness, the '456 patent would have to teach or suggest all elements of the rejected claims in combination with routine skill. Moreover, there would have to have been a reasonable expectation of the invention's success at the time of the invention. Again, one element of each rejected claim is a method of treating sickle cell disease in a subject comprising administering an antiviral agent to the subject. Thus, at the very least, the '456 patent, in combination with routine skill, would have to teach or suggest this element.

This it fails to do. Thus, the '456 patent, in combination with routine skill, does not teach or suggest a method of treating sickle cell disease in a subject comprising administering an antiviral agent to the subject to inhibit sickling of a cell in the subject, and thus does not teach or suggest all elements of the rejected claims. The Examiner failed to show how the '456 patent, combined with routine skill, would motivate one to arrive at the claimed invention, and reasonably expect its success.

Accordingly, the Examiner has failed to establish the prima facie obviousness of claims 1, 10, 13-15 and 17-19 over the '456 patent. For the same reasons, applicants alternatively maintain that the rejected claims would not have been obvious over the '456 patent.

In view of the above remarks, applicants maintain that claims 1, 10, 13-15 and 17-19 satisfy the requirements of 35 U.S.C. §103(a).

Summary

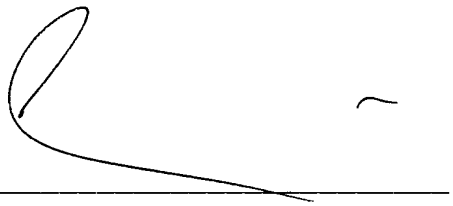
For the reasons set forth hereinabove, applicants respectfully request that the Examiner reconsider and withdraw the various grounds rejection and earnestly solicit allowance of the now pending claims, i.e. claims 1, 10 and 13-19.

If a telephone interview would be of assistance in advancing prosecution of the subject application, applicants'

undersigned attorneys invite the Examiner to telephone them at the number provided below.

No fee, other than the enclosed $210.00 fee for a two-month extension of time, is deemed necessary in connection with the filing of this Amendment. However, if any additional fee is required, authorization is hereby given to charge the amount of any such fee to Deposit Account No. 03-3125.

Respectfully submitted,



I hereby certify that this correspondence is being deposited this date with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

10/17/03

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